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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/499,423	07/07/1995	CAREY V. CAMPBELL	MP/84	2478
7590	09/23/2003		EXAMINER	
WAYNE D HOUSE W L GORE AND ASSOCIATES INC 551 PAPER MILL ROAD P O BOX 9206 NEWARK, DE 197149206			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	34

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/499,423	Applicant(s) Campbell et al.
	Examiner Brian Pellegrino	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Jul 11, 2003
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1, 3-7, 9-33, 35, 42-44, 46-66, 74-77, 79-88, and 91-97 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 3-7, 9-33, 35, 42-44, 46-66, 74-77, 79-88, and 91-97 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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DETAILED ACTION

Claim Objections

1. Claims 35,79-81 are objected to because of the following informalities: these claims ultimately depend from canceled claims (34,78). Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 86-88,91,95-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldfarb (6436135). Goldfarb discloses a tube of PTFE (col. 3, lines 40-55) that is fully capable of having its circumference increase with blood pressure application. The prosthesis is for use as a vascular graft, col. 1, lines 3-5. The graft is fully capable of being “adapted for” use as an endoluminal graft. The tube has a wall thickness about 0.25mm, col. 7, lines 9, 10. Regarding claim 91, the examiner asserts that the claimed physical properties (in this case, recoil) are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art.

3. Claims 1,3-7,9-17,19-31,33,35,42-44,46-66,74-77,79-88,91-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Shannon et al. (5641373). Shannon et al. disclose a tube

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base made of porous PTFE and is covered by one or more layers of porous PTFE material, col. 2, lines 21-24. Shannon also discloses the device has a microstructure of nodes and fibrils, col. 1, lines 19-30. The wall thickness has a measurement of about 0.1mm, see col.4, lines 51-53. The graft can be anchored via a stent, col. 11, lines 8-14 and also sutured, line 55. Regarding claims 17 and 31, since the graft is inherently capable of expanding to a second circumference, it is fully capable of having a tapered profile upon expansion in a tapered vessel. The limitation recited in claim 1, of applying internal pressure up to a second circumference such that the tube "limits further growth in the second circumference to remain substantially unchanged" or in claim 33, "limits further growth to *substantially* the second circumference" fails to distinguish the expansion beyond the second circumference as being different from the first to second circumferential expansion. Therefore, the claim language reads on a further expansion up to the second circumference. With respect to claims 10-13,42-44,46-66, 74-77,79-88,91-94, the examiner asserts that the claimed physical properties (in this case, recoil) are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. Shannon does disclose that the enlargement of the graft is at least permitted to 5% upon a force exerted on the tube, col. 8, lines 51-54. It would be inherent that the graft is also capable of recoiling which would be the same percentage as what the graft was permitted to expand at. This falls within the claimed range of minimal recoil of 7% or less.

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4. Claims 18,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon et al. '899 in view of Hughes et al. (4728328). Shannon et al. is explained *supra*. However, Shannon does not disclose a tube that is branched with three ends. Hughes et al. teach a tubular prosthesis that is branched with three ends, Fig. 12. It would have been obvious to one of ordinary skill in the art to use the branched tubular form as taught by Hughes with the prosthesis of Shannon in a vessel such as the trachea requiring replacement to the two bronchi.

5. Claims 92-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb '135. Goldfarb is explained *supra*. However, Goldfarb does not disclose the tube having minimum recoil at 14% or less. It would have been obvious matter of design choice to modify the tubular graft of Goldfarb and have the minimal recoil at 14% or less, since applicant has not disclosed that having the recoil percentage provides an advantage, solves any stated problem or is for any particular purpose. One of ordinary skill, furthermore, would have expected Applicant's invention to perform equally well with any recoil of the Goldfarb tube or the claimed 14% or less since both perform the same function as permitting blood flow through without bursting.

Response to Arguments

6. Applicant's arguments filed 07/11/03 have been fully considered but they are not persuasive. Regarding the remarks about the Shannon reference not disclosing a tube with limited recoil, because the Patent and Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed subject matter is not anticipated or

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unobvious, the examiner properly shifts the burden to applicants to show unanticipated or unobvious differences exist, Ex parte Phillips, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93). Since the Shannon PTFE tube covered with PTFE film is the same material as the claimed device, it must possess the same properties.

In response to applicant's argument that the Goldfarb reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., less recoil as a result of some preparation method of the material) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 7am to 4:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for this group is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceedings should be directed to the group receptionist whose telephone number is (703) 308-0858.



Brian E. Pellegrino

September 22, 2003



Paul Prebilic
Primary Examiner
TC 3700, AU 3738